

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC., and  
BAXTER HEALTHCARE CORPORATION,

Defendants.

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BAXTER HEALTHCARE CORPORATION

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC., and  
BAYER HEALTHCARE LLC,

Counterclaim Defendants.

C.A. No. 05-349-GMS

JOINT PROPOSED FINAL JURY INSTRUCTIONS

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**1 GENERAL INSTRUCTIONS**

**1.1 INTRODUCTION (STIPULATED)**

Members of the jury, I will now instruct you about the law that you must follow in deciding this case.

I will start by reminding you about your duties as jurors and the instructions you heard at the beginning of the case.

I will then explain the positions of the parties and the law you will apply in this case.

Lastly, I will explain the rules that you must follow during your deliberations in the jury room and the possible verdicts that you may return.

Please listen very carefully to everything that I say.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 1.1 (2004) .

**1.2 JURORS' DUTIES (STIPULATED)**

Remember your duties as jurors as I explained them to you at the beginning of the case. You must decide what the facts are from the evidence you saw and heard in court. Nothing I have said or will say should influence your determination of the facts in any way. Do not guess or speculate, and do not be influenced in any way by any personal feeling of sympathy for, or prejudice against, either side in this case. All parties are entitled to the same fair and impartial consideration.

You must also take the principles of law that I will now explain to you and apply them to the facts in reaching your verdict. You are bound by the oath you took to follow my instructions, even if you personally disagree with them.

All of my instructions are important, and you should consider them together as a whole. This includes the instructions that I gave you when we started and during trial. I will not repeat my earlier instructions about evidence and how to weigh and consider it. You have copies of these instructions, however, and you should refer to them as you feel necessary.

Perform these duties fairly. Do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 1.2 (2004).

**1.3 CHARTS AND SUMMARIES ADMITTED IN EVIDENCE (STIPULATED)**

The parties presented exhibits in the form of charts and summaries. I decided to admit some of these charts and summaries in place of the underlying evidence that they represent in order to save time and avoid unnecessary inconvenience. If I did so, you should consider these charts and summaries as you would any other evidence.

Authority: Third Circuit Model Civil Jury Instructions at 2.7 (rev. 08/06) (modified).



**1.4 CHARTS AND SUMMARIES NOT ADMITTED IN EVIDENCE  
(STIPULATED)**

Some charts and summaries that were be used by the parties during trial were not admitted into evidence. These charts and summaries were shown to you to make the other evidence more meaningful and to aid you in considering the evidence. They are no better than the testimony or the documents upon which they are based, and are not themselves independent evidence. Therefore, you are to give no greater consideration to these charts or summaries than you would give to the evidence upon which they are based.

It is for you to decide whether the charts or summaries correctly present the information contained in the testimony and in the exhibits on which they are based. You are entitled to consider the charts or summaries if you find that they are of assistance to you in analyzing the evidence and understanding the evidence.

Authority: *Leapfrog Enterprises Inc. v. Fisher-Price, Inc.*, Case No. 03-927-GMS, Final Jury Instructions, as read in Court on May 24, 2005, p.7.

### **1.5 BURDENS OF PROOF (STIPULATED)**

Talecris has the burden to prove its claim of patent infringement and its claim of damages by a preponderance of the evidence. That means Talecris must produce evidence that, when considered in light of all the facts, leads you to believe that what Talecris claims is more likely true than not. To put it differently, if you were to put Talecris' and Baxter's evidence on the opposite sides of a scale, the evidence supporting Talecris' claims would have to make the scales tip somewhat on its side.

In addition, Talecris must prove its claim of willful infringement by clear and convincing evidence and not by a preponderance of the evidence, the standard that applies to Talecris' other claims in this case. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a fact is highly probable. Proof by clear and convincing evidence is thus a higher burden than proof by a preponderance of the evidence.

Baxter has the burden to prove that claims 1 and 7 of the '191 patent are invalid and unenforceable by clear and convincing evidence.

Finally, keep in mind that the standard in criminal case, "proof beyond a reasonable doubt," does not play any part in this case, and you should, therefore, not consider it at all in your deliberations.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 1.3 (2004) (modified).

**2 THE PARTIES' CONTENTIONS (DISPUTED)**

I will now summarize the issues that you must decide and for which I will provide instructions to guide your deliberations. You must decide the following issues:

1. Whether Talecris has proven by a preponderance of the evidence that Baxter literally infringes claim 7 of the '191 patent by importing into the United States and/or offering to sell, selling, or using within the United States Baxter's GAMMAGARD® Liquid product, which Talecris alleges is made by the '191 patented process.
2. If you find that Baxter has infringed claim 7 of the '191 patent, whether Talecris has proven by clear and convincing evidence that Baxter's infringement of the '191 patent was willful.
3. Whether Baxter has proven by clear and convincing evidence that claims 1 and 7 of the '191 patent are invalid for anticipation.
4. Whether Baxter has proven by clear and convincing evidence that claims 1 and 7 of the '191 patent are invalid for obviousness.
5. Whether Baxter has proven by clear and convincing evidence that claims 1 and 7 of the '191 patent are invalid for lack of written description.
6. **[Whether Baxter has proven by clear and convincing evidence that claims 1 and 7 are invalid for indefiniteness.]<sup>1</sup>**

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<sup>1</sup>Talecris objects to Baxter's proposed contention regarding indefiniteness as irrelevant based on the Court's grant of summary judgment in favor of Talecris that the asserted claims of '191 patent are not indefinite. Baxter's insistence on including any mention of its now-defunct indefiniteness defense flies in the face of this Court's summary judgment ruling and is an entirely improper attempt to include a Motion for Reconsideration in these

7. Whether Baxter has proven by clear and convincing evidence that the '191 patent is unenforceable for failure to disclose material information.
8. If you find that claim 7 of the '191 patent is valid and infringed and the '191 patent is enforceable, whether Talecris has proven its measure of damages by a preponderance of the evidence.

In a few minutes, I will give you a detailed explanation for these matters.

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**Joint Proposed Jury Instructions.**

**3      INFRINGEMENT (STIPULATED)**

At the beginning of the trial, you watched a video which gave you some information about patents and the patent system and a brief overview of the patent laws. If you would like to review a text copy of the video or any of my earlier instructions at any time during your deliberations, they will be available to you in the jury room.

As I stated before, Talecris alleges that Baxter infringes claim 7 of the '191 patent. If anyone imports into the United States or offers to sell, sells, or uses within the United States a product that is made by a process covered by a patent claim without the patentee's permission, that person is said to *infringe* the patent. Talecris alleges that Baxter's manufacturing process to make GAMMAGARD® Liquid in Europe infringes claim 7 of the '191 patent and that Baxter imports GAMMAGARD® Liquid into the United States and/or offers to sell, sells, or uses GAMMAGARD® Liquid within the United States.

I will now instruct you on the specific rules you must follow in deciding whether Talecris has proven that Baxter has infringed claim 7 of the '191 patent.

Authority:      Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.1 (2004) (modified); 35 U.S.C. § 271(g).

### **3.1 PATENT CLAIMS**

#### **3.1.1 PATENT CLAIMS - GENERALLY (DISPUTED)**

To decide whether Baxter has infringed the '191 patent, you will have to understand the patent "claims." As you will recall from the video you watched at beginning of the trial, the claims of a patent are the numbered sentences at the end of a patent. The claims describe the invention made by the inventor. That is what the patentee owns and what the patentee may prevent other from making, using, or selling. Claims may describe processes for making or using a product. Only the claims of the patent can be infringed. The '191 patent also includes a Figure and discussions of examples of the invention, but neither the Figure nor the examples can be infringed. You should not compare Baxter's manufacturing process with any specific example set out in the '191 patent or with any manufacturing process used by Talecris. Rather, you must only compare Baxter's manufacturing process with claim 7 of the '191 patent when making your decision regarding infringement.

**[Each claim of a patent represents a separate protection given to a patentee.]<sup>2</sup>**

The law does not require infringement of all the claims in a patent. There is infringement if a single claim of the patent has been infringed and possible damages resulting from a finding of infringement.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.2.1 (2004); Judge Sleet's Preliminary Jury Instructions - Patent, available at <http://www.ded.uscourts.gov/GMSmain.htm> (Rev. 01/18/2006) (modified).

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<sup>2</sup>Baxter objects to Talecris' proposed language in brackets as cumulative and unnecessary and prejudicial in violation of Federal Rule of Evidence 403. The frequent reiteration of the patentee's rights and protection of its patent could unfairly bias the jury towards a finding of infringement, to Baxter's prejudice. *See* Fed. R. Evid. 403. Baxter respectfully requests that this sentence be excluded from the instruction. In the alternative, Baxter asks that the following sentence be given to neutralize and fairly present the case: "A company accused of infringement has the right to deny infringement for each claim."

Talecris responds that Baxter's objection is not well founded, particularly in a case such as this where one claim - Claim 7 - is being asserted for infringement and two claims - Claims 1 and 7 - are being asserted by Baxter for invalidity. It is essential that the jury is instructed that each claim stands alone in order to prevent juror confusion when rendering a verdict on infringement and invalidity, and to accurately reflect the law. Were this sentence to be excluded from the instruction, it would be to Talecris' great prejudice.

### **3.1.2 PATENT CLAIMS - DEPENDENT AND INDEPENDENT (STIPULATED)**

Claims are typically divided into parts called “elements” or “steps” in a process patent. For example, a claim that covers the invention of a table may recite the tabletop, four legs, and the glue that secures the legs to the tabletop. The tabletop, legs, and glue are each a separate element of the claim.

There are two types of patent claims: independent claims and dependent claims. An independent claim does not refer to any other claim of the patent. In simple terms, an independent claim stands on its own two feet. An independent claim is read alone to determine the elements that must exist to infringe the claim. Claim 1 is the only independent claim of the ‘191 patent.

A dependent claim refers to at least one other claim in the patent. A dependent claim includes all of the elements in the claims to which it refers. Therefore, to determine what a dependent claim covers, you must look at both the elements of the dependent claim and the claim or claims to which it refers.

Claim 7 of the ‘191 patent is a dependent claim. It refers to claim 1. For Baxter’s manufacturing process to infringe dependent claim 7, the manufacturing process must have all of the elements of both claim 7 and claim 1.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.2.2 (2004).



### **3.1.3 OPEN-ENDED OR “COMPRISING” CLAIMS (DISPUTED)**

#### **Talecris’ Proposed Instruction 3.1.3:**

The beginning or preamble to claim 1 uses the transitional word “comprising” in the phrase, “A method of treating a solution of antibodies which may have virus activity, the method comprising...” “Comprising” means “including” or “containing.” That is, if you find that Baxter’s manufacturing process contains all of the steps in claim 1, claim 1 is infringed - any additional steps are irrelevant.

For example, a claim to a table *comprising* the three elements of a tabletop, legs, and glue would be infringed by a table that includes those elements, even if the table also includes additional elements such as wheels on the table’s legs.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.3.3 (2004).

**Baxter's Objection to Talecris' Proposed Instruction 3.1.3:**

Baxter objects to Talecris' proposed instruction as misleading and an inaccurate statement of the law. *See, e.g., Woodson v. Scoot Paper Co.*, 109 F.3d 913, 929-931 (3d Cir. 1997). While it is true the use of the transitional word "comprising" allows for additional steps, such use "does not free the claim from its own limitations." *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001); *see also Spectrum Int'l Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998). Accordingly, not all additional steps are irrelevant as suggested by Plaintiffs' proposed instruction. If any additional step negates a required element of Claim 1, then Claim 1 cannot be infringed. *See Kustom Signals*, 264 F.3d at 1332. Therefore, Baxter offers as an alternative its proposed jury instruction, which fairly and accurately states the law.

**Baxter's Proposed Instruction 3.1.3:**

The preamble to Claim 1 uses the transitional word “comprising.” The word “comprising” means “including the following but not excluding others.” If you find that Baxter’s manufacturing process includes all of the elements in Claim 1, for example, the fact that Baxter’s manufacturing process might include additional process steps would not avoid literal infringement as a general rule.

However, there is one exception to this general rule. If the inclusion of additional steps in Baxter’s manufacturing process bars the possibility of meeting another required element of Claim 1, then you cannot find infringement.

For example, there might be a claim to “a process of cleaning brightly-colored clothes while preserving their color, comprising washing the clothes with cold water and regular soap.” Such a claim would be infringed by a cleaning process that washes clothes with cold water and regular soap and also adds fabric softener or starch because it is a comprising claim and permits other steps. However, a process that washes clothes with cold water and regular soap but also adds bleach, which fades bright colors, would not infringe the claimed process, even though it is a comprising claim, because it does not meet the “preserving their color” limitation.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 3.3.3 (2004) (modified); AIPLA’s Model Patent Jury Instructions, at 3.7 (Rev. Feb. 2006) (modified); *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001); *Spectrum Int’l. Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed. Cir. 1986).

**Talecris' Objection to Baxter's Proposed Instruction 3.1.3:**

Talecris objects to Baxter's proposed instruction in its entirety because it is misleading and will confuse the jury. Baxter's cleaning clothes example unnecessarily complicates the instruction and is likely to confuse the jury. Talecris requests that its proposed instruction be given to the jury instead of Baxter's proposed instruction. Talecris' proposed instruction comports with D. Del. Model Instructions and accurately states the law. Baxter's does not as it, *inter alia*, confuses additional unclaimed activities, with claim elements.

**3.1.4 THE COURT DETERMINES WHAT PATENT CLAIMS MEAN (DISPUTED)**

It is the Court's duty under the law to define what the patent claims mean. I have made my determinations, and I will now instruct you on the meaning of certain claim terms. You must use the meaning that I give you for each patent claim to make your decisions if the claim is infringed or invalid. You must ignore any different definitions used by the witnesses or the attorneys.

It may be helpful to refer to the copy of the '191 patent that you have been given as I discuss the claims at issue here. For example, if you look at the '191 patent, the claims of the patent are on the last page, starting at column 11, line 34. I have determined the meaning of the following terms:

1. The term "any virus activity" has its plain and ordinary meaning.
2. The term "under conditions ... resulting in an increased level of anticomplement activity" has its plain and ordinary meaning.
3. The term "under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity" has its plain and ordinary meaning.
4. The term "increased level of anticomplement activity" has its plain and ordinary meaning.
5. The term "increased anticomplement activity of the solution" has its plain and ordinary meaning.
6. The term "then incubating the solution of step a)" means "incubating a solution originating from step a) under conditions of controlled time, pH,

temperature, and ionic strength, wherein additional steps may be performed prior to said incubating.”

- [7. The term “about 60 CH<sub>50</sub> units/mL” is construed to mean “about 60 CH<sub>50</sub> units/mL, wherein one unit of ACA activity (one CH<sub>50</sub> unit) is defined as the amount of protein capable of activating 50% of the complement in an optimally titrated complement and red blood cell hemolysin system.”
8. The term “about 45 CH<sub>50</sub> units/mL” is construed to mean “about 45 CH<sub>50</sub> units/mL, wherein one unit of ACA activity (one CH<sub>50</sub> unit) is defined as the amount of protein capable of activating 50% of the complement in an optimally titrated complement and red blood cell hemolysin system.”]<sup>3</sup>
9. The term “anticomplement activity” means “the measure of the ability of antibodies to bind complement.”
10. The term “acceptable level suitable for intravenous administration” has its plain and ordinary meaning.
11. The term “ionic strength” means “the summation:  $I=1/2\sum(c_i z^2)$  where  $c_i$  is the concentration of each type of ion (in moles l-1) and  $z$  is its charge.”

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<sup>3</sup>Talecris objects to Baxter’s proposed language because the terms “about 60 CH<sub>50</sub> units/mL” and “about 45 CH<sub>50</sub> units/mL” do not appear in claims 1 or 7, and therefore, their inclusion in this instruction is irrelevant and will confuse the jury, to Talecris’ great prejudice given the Court’s rulings on Talecris’ Motions *in Limine* Nos. 3 and 4. The only possible reason for including these terms herein would be for Baxter to again attempt to reargue and/or circumvent the Court’s claim construction of other terms in this case.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 3.3.3 (2004) (modified).

**3.1.5 PLAIN AND ORDINARY MEANING (DISPUTED)**

Plain and ordinary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art at the time of the invention. This is based on the understanding that patents are addressed to and intended to be read by people of skill in the art, who read the claims of the patent in the context of the specification and prosecution history of the patent. You should determine plain and ordinary meaning in this context[, **that is, in the context of the patent specification and prosecution history as understood by people of ordinary skill in the art.**]<sup>4</sup>

Authority: *Philips v. AWH Corp.*, 1313; *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1303, 1313, 1319, 1324 (Fed. Cir. 2005); *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc); *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878 (Fed. Cir. 1988).

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<sup>4</sup>Talecris objects to the remainder of this sentence as cumulative, unnecessary, and confusing to the jury.



**3.1.6 LEVEL OF ORDINARY SKILL (BAXTER'S PROPOSED INSTRUCTION)**

You must determine the level of ordinary skill in the art to which the claimed invention pertains. You must determine this level of skill as of September 22, 1995. Factors to be considered in determining the level of ordinary skill in the pertinent art include the educational level of the inventor, the types of problems encountered in the art, the prior art patents and publications, the activities of others and prior art solutions to the problems encountered by the inventor, the sophistication of the technology, and the education of others working in the field.

Talecris contends that a person of ordinary skill in the art is one or more scientists, each with an earned doctoral degree and several years of postdoctoral experience in the fields of antibody biochemistry, protein purification or process manufacturing, and/or clinical treatment of humans using IGIV.

Baxter contends that a person of ordinary skill in the art is a process chemist, biochemist, or immunologist (or the equivalent) with either: (1) a Bachelor's or Master's degree in chemistry, biology, biochemistry, immunology, or related field, and several years of experience in one or more of the following: (a) the purification of blood proteins, including fractionation; (b) virus removal or inactivation techniques, including solvent/detergent treatment and low pH incubation; and (c) the complement system and/or ACA, including how to measure and lower ACA; or (2) the equivalent of (1). This level of ordinary skill could be met either by an individual or by a group of people who satisfy the above criteria.

Based on the factors listed and the evidence presented, you must determine the level of ordinary skill in the art.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8.3 (2004) (modified); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006); *Orthopedic Equipment Co. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983); AIPLA's Model Patent Jury Instructions (2005).

**Talecris' Objection to Baxter's Proposed Instruction 3.1.6:**

Talecris objects to the placement and content of this instruction in its entirety. Talecris' proposed instruction (*see* Talecris Proposed Instruction 4.4.4 below) accurately states the law, and further, it is inappropriate for the Court to instruct the jury on any contentions of parties - the jury is to be instructed on the law to apply to the facts. Were the Court to instruct the jury as Baxter proposes, there is a great risk that the fact-finding function will be taken away from the jury. The parties should be put to their proofs. Talecris requests that its instruction on level of ordinary skill be given after Instruction No. 4.4.3 "Differences Over the Prior Art".

**3.2 INFRINGEMENT - BURDEN OF PROOF (STIPULATED)**

To prove infringement of the '191 patent, Talecris must persuade you by a preponderance of the evidence that Baxter has infringed claim 7 of the '191 patent.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.1 (2002).

### 3.3 PATENT INFRINGEMENT

#### 3.3.1 DIRECT INFRINGEMENT (DISPUTED)

Now that I have told you about the patent claims, I am now going to give you some instructions on the specific rules for infringement. **[A patentee may enforce its right to stop others from importing into the United States or offering to sell, selling, or using within the United States a product which is made by a process patented in the United States.]<sup>5</sup> [A company accused of infringement has the right to deny infringement in federal court.]<sup>6</sup>**

Here, Talecris has sued Baxter and has alleged that Baxter's GAMMAGARD® Liquid is made in Europe by a process that directly infringes claim 7 of the '191 patent. Talecris further alleges that Baxter imports GAMMAGARD® Liquid into the United States and sells

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<sup>5</sup>Baxter objects to this language in brackets as cumulative and unnecessary and prejudicial in violation of Federal Rule of Evidence 403. The frequent reiteration of the patentee's rights could unfairly bias the jury towards a finding of infringement to Baxter's prejudice. Fed. R. Evid. 403. By this point in time, the jury has been informed through the FJC video, the preliminary instruction, and previous final jury instructions, through all of them about the patentee's rights. Baxter therefore asks that this sentence be excluded. In the alternative, Baxter requests that the bolded language below be also given to neutralize and fairly present the case.

<sup>6</sup>Talecris objects to this language because it is superfluous and a waste of time. The jury will have already understood from the FJC Video that Baxter has the right to deny infringement, and certainly will understand that Baxter is denying infringement by the time it is being charged prior to deliberations. Further, this language is not in the model instruction; it is not necessary to vary from the model in this case. Finally, the sentence need not be given to "neutralize" what is nothing more than accurate articulation of a patentee's rights under the law.

GAMMAGARD® Liquid within the United States. **[Baxter has denied infringement.]**<sup>7</sup>

Deciding whether claim 7 has been directly infringed is a two-step process. First, the meaning of claim 7 is determined as a matter of law. That job is for the Court, and I have just told you what the key terms of claim 7 mean as a matter of law. In the second step, claim 7 must be compared to the accused process to determine whether every element of the claim is found in the accused process. The element-by-element comparison is your responsibility as the jury for this case.

A patent claim may be directly infringed if it is literally infringed. I will explain literal infringement shortly.

Keep in mind that intent to infringe, actual knowledge of a patent, or knowledge that you are infringing a patent, is not part of a claim of patent infringement. In short, direct infringement can be established even if Baxter had a good faith belief that its actions were not infringing the '191 patent and even if Baxter did not know of the '191 patent.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.3 (2004) (modified); 35 U.S.C. § 271(g).

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<sup>7</sup>See footnote 5. This sentence is also cumulative of Baxter's previously proposed sentence, addressed in footnote 5.

**3.3.2 DIRECT INFRINGEMENT – LITERAL (STIPULATED)**

Claim 7 of the '191 patent is literally infringed if Baxter's GAMMAGARD® Liquid manufacturing process includes every element or step in claim 7, which includes the elements of claim 1. If Baxter's manufacturing process omits any element or step recited in claim 7, which includes the elements of claim 1, Baxter does not literally infringe claim 7.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.3.1 (2004) (modified).

**3.3.3 DETERMINATION OF INFRINGEMENT (STIPULATED)**

If you find that Talecris has proven by preponderance of the evidence that each element of claim 7 is present literally in Baxter's GAMMAGARD® Liquid manufacturing process, then you must find that Baxter's GAMMAGARD® Liquid manufacturing process literally infringes claim 7.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.12 (2004) (modified).



### 3.4 WILLFUL INFRINGEMENT (DISPUTED)

#### Talecris' Proposed Instruction 3.4:

Talecris contends that Baxter has willfully infringed the '191 patent.

When a company becomes aware that a patent may have relevance to its activities, that company has a duty to exercise due care and investigate whether or not its activities infringe any valid claim of the patent. If that company does not do so and infringes the patent claims, then the infringement is willful.

The issue of willful infringement is not relevant to your decision of whether or not there is any infringement, but rather concerns the amount of damages to which Talecris is entitled. That is, a finding of willful infringement may, in certain circumstances, entitle the patentee to increased damages. If you decide that Baxter willfully infringed claim 7 of the '191 patent, then it is my job to decide whether or not to award increased damages to Talecris.

Although, as I explained before, Talecris must prove infringement of the '191 patent by a preponderance of the evidence, Talecris' burden of proving that the infringement of the '191 patent was willful is the higher burden of clear and convincing evidence. Therefore, if you find on the basis of the evidence and the law as I have explained it that Baxter's accused process infringes claim 7 of the '191 patent, you must further decide whether Talecris has proven that Baxter's infringement was willful. To establish willful infringement, Talecris must prove two things with clear and convincing evidence:

One, that Baxter was aware of the '191 patent; and

Two, that Baxter did *not* have a reasonable good faith belief that the patent was either

invalid, or that the patent was not infringed.

To determine whether Baxter acted with a reasonable good faith belief or whether Baxter willfully infringed the '191 patent, you must consider all of the facts, including the strength of the defenses raised by Baxter in this trial and the following factors:

1. In designing the process accused of infringement, whether Baxter intentionally copied Talecris' invention that is covered by the '191 patent, or whether Baxter instead tried to "design around" the patent by designing a process that Baxter believed did not infringe the claims of the '191 patent. Evidence of copying is evidence of willful infringement; on the other hand, evidence of a good faith effort to "design around" the claims is evidence that the infringement was not willful.
2. When Baxter became aware of the patent, whether Baxter formed a good faith belief that the patent was invalid or that the patent was not infringed. Baxter's defenses prepared for trial cannot alone be determinative of whether Baxter acted with a reasonable good faith belief.

Keep in mind that a determination by you that Baxter has infringed the '191 patent does not automatically mean that the infringement was willful. As I have explained, the infringement is not willful if Baxter had a good faith belief that it did not infringe, or that the '191 patent was invalid, and if its belief was reasonable under the circumstances.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.13 (2004) (modified); Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 3.12 (2002); *Black & Decker Inc. v. Robert Bosch*

*Tool Corp.*, 2006 U.S. Dist. LEXIS 92882 (N.D. Ill. Dec. 22, 2006) (citing *Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.* 246 F.3d 1336, 1356 (Fed. Cir. 2001)).

**Baxter's Objection to Talecris' Proposed Instruction 3.4:**

Baxter objects to this instruction in entirety as misleading, prejudicial, and biased in favor of the patentee in violation of Federal Rule of Evidence 403. Talecris' proposed instruction varies from the 2004 Draft Model Instruction to place an undue emphasis on the accused infringer's duty to exercise due care in order to create a heightened duty that is not based in law. None of Plaintiffs' cited authorities support such heightened duty. Furthermore, Baxter objects to the following portions of Talecris' proposed instructions as misleading and inaccurate statements of the law and fact:

(1) The entire third paragraph is misleading and prejudicial as it incorrectly states that Plaintiffs are entitled to damages. The paragraph is not in the 2004 Draft Model Instructions which replaced the prior version of model instructions nor in the lone case authority cited by Talecris, *Black & Decker Inc. V. Robert Bosch Tool Corp.*, 2006 U.S. Dist. LEXIS 92882 (N.D. Ill. Dec. 22, 2006).

(2) The sentence "Baxter was aware of the '191 patent" is misleading and inaccurate because the law requires actual notice of the issued patent and not mere or constructive awareness. *See Imonex Servs., Inc. v. W.H. Munzprufer Dietmar Trenner GmbH*, 408 F.3d 1374, 1377 (Fed. Cir. 2005); *see also Black & Decker*, 2006 U.S. Dist. LEXIS 92882, at \*8 (citing *nCube Corp. v. Seachange Int'l, Inc.*, 436 F. 3d 1317, 1324 (Fed. Cir. 2006)).

(3) Talecris' proposed instruction on the design-around is misleading and without any basis in case authority; and

(4) Talecris' new proposed instruction(without the striked through words) – "Baxter's defenses prepared for trial ~~are not equivalent to the competent opinion of counsel of~~

~~noninfringement or invalidity and cannot alone be determinative of whether Baxter acted~~  
with a reasonable good faith belief” – is misleading and inaccurate statement of law. Legal  
defenses prepared for trial alone was held determinative for a finding against willful  
infringement. *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 f.2d 508, 510-511  
(Fed. Cir. 1990). Plaintiffs’ case authority does not support this revision as it arose in the  
context of an argument regarding competent opinion of counsel, which Baxter has never  
raised. Consequently, Baxter offers as an alternative its proposed jury instruction, which  
fairly and accurately states the law.

**Baxter's Proposed Instruction 3.4:**

If you find on the basis of the evidence and the law as I have explained it that Baxter's process infringes Claim 7, you must further decide whether or not Talecris has proven by clear and convincing evidence that Baxter's infringement was willful. To establish willful infringement, Talecris must prove two things with clear and convincing evidence:

1. first, that Baxter had actual knowledge of the '191 patent; and
2. second, that Baxter acted without having a reasonable good faith basis for concluding that it did not infringe the '191 patent or that the '191 patent was invalid or that the '191 patent was unenforceable.

To determine whether Baxter acted with reasonable good faith belief, you must consider the totality of the circumstances, including the strength of the defenses raised by Baxter in this trial and the following factors:

- a. whether Baxter intentionally copied the claimed invention or a product covered by Talecris' patent or whether, in contrast, Baxter, as a competitor of Talecris, developed a product that is functionally competitive with Talecris' product but did not set out to copy it, even if patent infringement ultimately is found,
- b. whether Baxter, when it learned of the '191 patent, made reasonable examination of the facts and law relating to infringement, invalidity or unenforceability issues;
- c. whether Baxter had a substantial defense to alleged infringement and reasonably believed the defense would be successful if litigated; and

Keep in mind that a determination by you that Baxter has infringed the '191 patent does not automatically mean that the infringement was willful. As I have explained, the infringement is not willful if Baxter had a good faith belief that it did not infringe or that the asserted patent claims were invalid or that the patent was unenforceable, and if its belief was reasonable under all the circumstances.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 3.13 (2004) (modified); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1347 (Fed. Cir. 2004) (en banc); *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510-11 (Fed. Cir. 1990); *King Instrument Corp. v Otari Corp.*, 767 F.2d 853, 867 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1016; *Radio Steel & Mfg. Co. v. MTD Products, Inc.*, 788 F.2d 1554, 1559 (Fed. Cir. 1986).

**Talecris' Objection to Baxter's Proposed Instruction 3.4:**

Talecris objects to Baxter's proposed instruction as contrary to applicable law. *See Black & Decker Inc. v. Robert Bosch Tool Corp.*, 2006 U.S. Dist. LEXIS 92882 (N.D. Ill. Dec. 22, 2006) (citing *Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.* 246 F.3d 1336, 1356 (Fed. Cir. 2001)). Talecris also objects to Baxter's proposed instruction because it is misleading, prejudicial, and biased in favor of Baxter.



**4      INVALIDITY (STIPULATED)**

Now I will instruct you on the law of invalidity. In considering invalidity, you must use the same claim meanings for the claim terms as you did in determining infringement. Baxter contends that claims 1 and 7 of the '191 patent are invalid for failure to satisfy the legal requirements of patentability. In particular, Baxter contends that claims 1 and 7 are invalid as anticipated, obvious, or for failure to satisfy the written description requirement. I will now instruct you on each of these defenses.

Authority:      Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4 (2004) (modified); *Eaton Corp. v. Rockwell Int'l Group*, 323 F.3d 1332, 1343 (Fed. Cir. 2003).

**4.1 PRESUMPTION OF VALIDITY (TALECRIS' PROPOSED INSTRUCTION)**

The granting of a patent by the Patent Office carries with it the presumption that the patent's subject matter is new, useful, and constitutes an advance that was not, at the time the invention was made, obvious to one of ordinary skill in the art. The law presumes, in the absence of clear and convincing evidence to the contrary, that the Patent Office acted correctly in issuing the patent. Nonetheless, once the validity of a patent has been put at issue, it is the responsibility of the jury to review what the Patent Office has done consistent with these instructions on the law.

Baxter has the burden of proving invalidity of claims 1 and 7 by clear and convincing evidence.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.1 (2004) .

**Baxter's Objection to Talecris' Proposed Instruction 4.1:**

Baxter objects to this instruction as misleading, prejudicial, and biased in favor of the patentee in violation of Federal Rule of Evidence 403. The form of Talecris' proposed instruction could unfairly bias the jury against a finding of invalidity by encouraging it to place undue emphasis on the presumption of validity, to Baxter's prejudice.

**4.2 DEFINITENESS UNDER 35 U.S.C. § 112 (BAXTER'S PROPOSED INSTRUCTION)**

I will now give you the standards by which to judge the legal adequacy of a patent disclosure, both specification and claims.

The asserted claims must be sufficiently definite that a person of ordinary skill in the art can determine the precise limits of the claimed invention. If a person of ordinary skill in the art would be unable to determine whether their activity infringes or not, then the claim is indefinite.

The disclosure should contain sufficient clues or guidance to provide objective standards by which a skilled artisan can determine the scope of the invention. When a word or phrase of degree such as “substantially equal to” is used, you must determine whether the patent disclosure provides some standard for measuring that degree. You must then determine whether people of ordinary skill in the art would understand what is covered when the claim is read in light of the disclosure. Experimentation needed to determine the limits of the claims of the patent is not necessarily a basis for holding the claims invalid.

Any asserted claim of the ‘191 patent is invalid for indefiniteness if its disclosure does not satisfy the standards above. Baxter contends, in particular, that the claim terms “acceptable level suitable for intravenous administration,” “increased level of anticomplement activity,” “then incubating the solution of step (a),” “reduced to an acceptable level” and “the increased anticomplement activity of the solution” are indefinite. If any of these terms is indefinite, then all asserted claims of the ‘191 patent are invalid.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.1 (2004); 35 U.S.C. § 112; *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351-52 (Fed. Cir. 2005). *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003); *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338 (Fed. Cir. 2003); *Seattle Box Co. v. Industrial Crating & Packing*, 731 F.2d 818, 826 (Fed. Cir. 1984).

**Talecris' Objection to Baxter's Proposed Instruction 4.2:**

Talecris objects to Baxter's Proposed Instruction 4.2 in its entirety as irrelevant. The Court granted summary judgment in favor of Talecris that the asserted claims of the '191 patent are not indefinite. Therefore, indefiniteness is no longer in the case and no jury instruction is necessary.

While Baxter has filed a Motion for Reconsideration regarding the Court's summary judgment decision, indefiniteness is currently not in the case and its inclusion in these instructions is entirely irrelevant.

If the Court grants Baxter's Motion for Reconsideration, Talecris reserves the right to further negotiate with Baxter concerning the substance of the indefiniteness instruction.

**4.3 THE WRITTEN DESCRIPTION REQUIREMENT (DISPUTED)****Baxter's Proposed Instruction 4.3:**

Baxter contends that claims 1 and 7 of the '191 patent are invalid because they lack an adequate written description. The patent law requires that a patent application contain an adequate written description of the invention to ensure that the inventor was in possession of the invention at the time the patent application was filed.

The specification and claims as originally filed must convey to people of ordinary skill in the art that Dr. Alonso had invented that which he ultimately claims in the '191 patent. The written description requirement is satisfied if people of ordinary skill in the art, reading the patent application as originally filed, would immediately discern the invention and all its limitations as finally claimed in the patent. Obvious variations of the invention are not considered part of the disclosure. No particular form of written description is required, but each limitation of a claim must be described.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.2 (2004) as noted; *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); *Turbocare Div. of Demag Delaval Turbomach. Corp., v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2002); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-90 (Fed. Cir. 1998); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

**Talecris' Objection to Baxter's Proposed Instruction 4.3:**

Talecris objects to this instruction in its entirety. Talecris' proposed instruction accurately states the law.

Baxter's proposed instruction misapplies Federal Circuit precedent to Talecris' prejudice. *See Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("One skilled in the art, reading the original disclosure, must 'immediately discern the limitation at issue'" in the claims.)



**Talecris' Proposed Instruction 4.3:**

Baxter contends that claims 1 and 7 of the '191 patent are invalid because they lack an adequate written description. The patent law requires that a patent application contain an adequate written description to ensure that the inventor was in possession of the invention at the time the patent application was filed.

The specification and claims as originally filed must convey to persons of ordinary skill in the art that the inventor had invented the subject matter that is spelled out in the claims that ultimately issued as a patent. However, a specification need not disclose what is well known in the art. The description must be sufficiently clear that persons of ordinary skill in the art will recognize that the inventor made the invention having each of the elements described in the claims.

That is, to prove claims 1 and 7 invalid for lack of an adequate written description, Baxter must prove by clear and convincing evidence that the patent application does not reasonably convey to a person of ordinary skill in the art that the inventor had possession of the invention (at the time of the application) as that invention was finally claimed in the issued patent. No particular form of written description is required, and the description need not be in the exact words of the claimed invention.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware (2004) p.36 (modified); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004).

**Baxter's Objection to Talecris' Proposed Instruction 4.3:**

Baxter objects to Talecris' proposed instruction as a misleading and inaccurate statement of the law, as it omits any reference to Federal Circuit law, which holds that "obvious variants" of the described invention are not considered part of the patent disclosure. *Turbocare Div. of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1119 (Fed. Cir. 2001); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

The written description requirement also requires that the description be sufficiently clear that persons of ordinary skill in the art be able to immediately discern the inventor's possession of the invention. *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Baxter objects that, in the absence of this language, Talecris' proposed instruction is misleading and an inaccurate statement of law.

#### 4.4 ANTICIPATION - GENERALLY (DISPUTED)

##### Stipulated:

Baxter contends that the invention covered by claims 1 and 7 of the '191 patent are invalid because it is not new. A person cannot obtain a patent on an invention if someone else has already made the exact same invention. In other words, the invention must be new. If it is not new, we say that it was "anticipated" by the prior art. Prior art is the legal term used to describe what others had done in the field before the invention was made, and may include other patents and applications, prior publications, and products, processes, or articles in public use. Prior art is the general body of knowledge in the public domain, such as articles or other patents before the invention was made. It is not necessary that the prior art has been available to every member of the public. It must have been available, without restriction, to that segment of the public most likely to make use of the prior art's contents. An invention that is "anticipated" by the prior art is not entitled to patent protection.

##### Baxter proposes:<sup>8</sup>

In determining whether a single item of prior art anticipates a patent claim, you should take into consideration not only what is expressly disclosed in the particular item of prior art, but also what necessarily, or inherently, occurred as a natural result of its practice. This is called "inherency." Inherency may result in the anticipation of entire inventions as well as individual limitations within an invention. Inherent anticipation, however, does not

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<sup>8</sup>Talecris objects to Baxter's proposed language because it does not properly delineate inherency in accord with applicable law. *See, e.g., Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378-79 (Fed. Cir. 2003); *Sandt Tech., Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001); *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380-81 (Fed. Cir. 2002).

require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. Thus, the prior use of the patented invention that was unrecognized can still be an invalidating anticipation.

Authority: 35 U.S.C. § 102; Draft Uniform Jury Instructions for Patent Cases for the District of Delaware at 4.5 (2004) (modified); *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377-79 (Fed. Cir. 2003); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001); *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560 (Fed. Cir. 1988); *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628 (Fed. Cir. 1987); *Tyler Refrigeration v. Kysor Indus. Corp.*, 777 F.2d 687 (Fed. Cir. 1985); AIPLA's Model Patent Jury Instructions (2005).

**Talecris proposes:<sup>9</sup>**

To prove that an invention is "anticipated," Baxter must prove by clear and convincing evidence that a single piece of prior art expressly or inherently describes or discloses all of the elements of the claimed invention.

When a prior art reference is silent about an asserted inherent characteristic, Baxter must put forth clear and convincing evidence that makes clear that the missing element is necessarily present in the thing described in the reference. Inherency may not be established by probabilities or possibilities.

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<sup>9</sup>Baxter objects that Talecris' proposed instruction presents a misleading and incomplete statement of the law. Inherency does not require that a person of ordinary skill in the art recognize that the missing element is necessarily present. Federal Circuit case law specifically holds that "[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art." *Mehl/Biophile Int'l. Corp. v. Palomar Medical Techs., Inc.*, 192 F.3d 1362, 1365-66 (Fed. Cir. 1999). Also, "[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Talecris' proposed language to the contrary would mislead the jury in violation of Federal Rule of Evidence 403.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware (2004) p.40 (modified); *Sandt Tech., Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001); *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380-81 (Fed. Cir. 2002).

**4.4.1 PRIOR PUBLIC KNOWLEDGE (STIPULATED)**

Baxter contends that claims 1 and 7 of the '191 patent were anticipated because others in the United States publicly knew of the claimed invention before the date of Dr. Alonso's invention. The date of Dr. Alonso's invention is presumed to be the filing date of the '191 patent application, which is September 22, 1995, but that date is to be determined by you, the jury, and there is a separate instruction providing guidance on that date.

Claims 1 and 7 are invalid if the invention recited in that claim was publicly known by others in the United States before Dr. Alonso invented it. If this is true, you must find claims 1 and 7 of the '191 patent invalid.

Authority: 35 U.S.C. § 102(a); Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.5.1 (2004) (modified).

#### **4.4.2 PRIOR PUBLICATION (STIPULATED)**

Baxter contends that claims 1 and 7 of the '191 patent were anticipated because the invention defined in those claims was described in a prior publication, such as an article or another patent. Claims 1 and 7 of the '191 patent are anticipated and invalid if the entire invention defined by those claims was described in a printed publication either: (1) before the date of Dr. Alonso's invention; or (2) before September 22, 1994, more than one year before the effective filing date of the '191 patent application.

For a printed publication to anticipate claims 1 and 7 of the '191 patent, Baxter must show that the printed publication, when read by a person of ordinary skill in the art, expressly or inherently embodies or discloses each element of the claim. The disclosure in the printed publication must be complete enough to enable one of ordinary skill in the art to practice the invention, without undue experimentation. In determining whether the disclosure is enabling, you should also take into account what would have been within the knowledge of a person of ordinary skill in the art at the time, and you may consider expert testimony and other publications that shed light on the knowledge such a person would have had at that time.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.5.4 (2004) (modified).

#### **4.4.3 DATE OF INVENTION (STIPULATED)**

Some categories of prior art refer to the date on which the inventor made his invention. This is called the “date of invention”. I will now explain to you how to determine this date.

There are two parts to the making of an invention. The inventor has the idea of the invention. This is referred to as “conception” of the invention. A conception of an invention is complete when the inventor has formed the idea of how to make and use every aspect of the claimed invention, and all that is required is that it be made without the need for any further inventive effort. The actual making of the invention is referred to as “reduction to practice.” An invention is said to be “reduced to practice” when it is made and shown to work for its intended purpose.

Under the patent laws, the date of invention is presumed to be the date that the patent application was filed. This is also referred to as “constructive reduction to practice.” In this case, that date is September 22, 1995. Ordinarily, prior art dated before the application filing date is prior art to the patent claims.

There are, however, two circumstances under which a patent or reference dated less than a year before the application filing date is not prior art. The first occurs when the inventor of the patent reduced the invention to practice before the date of the reference. A reference dated after the reduction to practice and less than a year before the application filing date is not prior art to the patent claims. Patents and references dated more than a year before the application filing date are always prior art.

The second circumstance occurs when the inventor conceived of the invention before



the date of the prior art and exercised reasonable diligence from just before the date of the art up to the date of the inventor's reduction to practice. In that case, a reference dated after the conception date is not prior art to the patent claims unless it is dated more than a year before the application filing date. Reasonable diligence means the inventor worked continuously on reducing the invention to practice. Interruptions necessitated by the everyday problems and obligations of the inventor or others working with him or her do not prevent a finding of diligence.

Authority: *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001); *Genentech Inc. v. Chiron Corp.*, 220 F.3d 1345, 1351 (Fed. Cir. 2000); *Cooper v. Goldfarb*, 154 F.3d 1321, 1326-31 (Fed. Cir. 1998); *Hyatt v. Boone*, 146 F.3d 1348, 1352-55 (Fed. Cir. 1998); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592-93 (Fed. Cir. 1997); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577-79 (Fed. Cir. 1996); *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994); *Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987); *Morgan v. Hirsch*, 728 F.2d 1449, 1452 (Fed. Cir. 1984).

#### 4.4.4 BAXTER'S CONTENTIONS (ANTICIPATION) (BAXTER'S PROPOSED INSTRUCTION)

Baxter contends that Claims 1 and 7 of the '191 patent are invalid because each is anticipated by at least one of the following items of prior art:

1. U.S. Patent No. 5,256,771 (Tsay) (1993) ("the Tsay reference");
2. Paul K. Ng., *et al.*, "Process-Scale Purification of Immunoglobulin M Concentrate," *Vox Sang* 65:81-86 (1993) ("the Ng reference");
3. EP 525 502 A1 (Gehring) (1992) ("the Gehring reference");
4. Piet, *et al.*, "The use of tri(n-butyl) phosphate detergent mixtures to inactivate hepatitis viruses and human immunodeficiency virus in plasma and plasma's subsequent fractionation," *Transfusion* 30(7) 591-598 (1990) ("the Piet reference");
5. Prince, *et al.*, "Failure of a human immunodeficiency virus (HIV) immune globulin to protect a chimpanzee against experimental challenge with HIV," *Proc. Natl. Acad. Sci. USA* 85:6944-6948 (1988) ("the Prince reference");
6. Biesert, *et al.*, "Virus validation of a new polyvalent intravenous immunoglobulin (Octagam)" *Vox Sang*. 67:S2 (1994); Abstract 0726, Octagam EU Brochure (1995); Octagam Israeli Brochure (1994) ("the Biesert/Octagam EU/Octagam Israeli reference");
7. Eriksson, *et al.* "Virus validation of plasma-derived products produced by Pharmacia, with particular reference to immunoglobulins," *Blood Coagulation and Fibrinolysis*, 5(3): S37-44 (1994) ("the Eriksson reference");

8. Venoglobulin-S product;  
Yang, Y.H. *et al.*, “Antibody Fc Functional Activity of Intravenous Immunoglobulin Preparations Treated with Solvent-Detergent for Virus Inactivation,” *Vox Sang.* 67:337-344;  
Uemura, Y., *et al.*, “Inactivation and Elimination of Viruses during Preparation of Human Intravenous Immunoglobulin *Vox Sang.* 67:246-254 (1994) (together, “the Venoglobulin/Yang/Uemura reference”);
9. Hämäläinen *et. al.*, “Virus Inactivation during Intravenous Immunoglobulin Production” *Vox Sang* 63:6-11 (1992) (“the Hämäläinen reference”).

**Talecris' Objection to Baxter's Proposed Instruction 4.4.4:**

Talecris objects to this instruction in its entirety and requests that it not be given to the jury. It is inappropriate for the Court to instruct the jury on any contentions of parties - the jury is to be instructed on the law to apply to the facts. Such an instruction takes the fact finding function away from the jury and there is also a significant risk of the jury thinking that the Court somehow endorses or is advocating for Baxter's positions.

#### 4.5 OBVIOUSNESS (DISPUTED)

Obviousness is an additional and separate basis from anticipation for finding a patent claim invalid. Unlike anticipation, obviousness may be shown by considering combinations of items of prior art.

In order to be patentable an invention must not be obvious to a person of ordinary skill in the art at the time the invention was made. The issue is not whether the claimed invention would be obvious to you as a layperson, to me as a judge, or to a genius in the art, but whether it would have been obvious to a person of ordinary skill in the art at the time it was made.

In determining obviousness or non-obviousness of each asserted claim of the '191 patent, you should take the following steps:

1. Determine the scope and content of the prior art relied upon by Baxter.
2. Identify the differences, if any, between each asserted claim of the '191 patent and the prior art.
3. Determine the level of ordinary skill in the pertinent art at the time the invention of the '191 patent was made.
4. Consider objective factors of non-obviousness, which I will describe to you in detail later.

Against this background, you must then decide whether the claimed subject matter would have been either obvious or non-obvious to a person of ordinary skill in the pertinent art. **[A claim is obvious, even if it is an improvement over the prior art, if it is nothing more than a predictable use of a combination of prior art elements according to their**

established functions. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.]<sup>10</sup>

Baxter's Authority: 35 U.S.C. § 103; Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8 (2004) (modified); *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*36 and 39-40 (April 30, 2007); *Pfizer, Inc. v. Apotex, Inc.*, 82 U.S.P.Q.2d 1321, 1333 (Fed. Cir. 2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289-90 (Fed. Cir. 2006); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 764 (Fed. Cir. 1988); *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); AIPLA Guide To Jury Instructions in Patent Cases.

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<sup>10</sup>Talecris objects to Baxter's proposed instruction as misleading, prejudicial, and an inaccurate statement of the law. Baxter's proposed language that states "even if it is an improvement over the prior art" is superfluous language because it will necessarily be an improvement over the prior art. Baxter's last sentence is from KSR, but it is confusing and circular; moreover, nothing in KSR indicates substantial variation from *Graham*.

**4.5.1 SCOPE AND CONTENT OF THE PRIOR ART (STIPULATED)**

In arriving at your decision on the issue of whether or not the claimed invention is obvious to one of ordinary skill in the art, you must first determine the scope and content of the prior art. This means you must determine what prior art is reasonably pertinent to the particular problem that the inventor faced. Prior art is reasonably pertinent if it is in the same field as the claimed invention or is from another field that a person of ordinary skill in the art would look to in trying to solve the problem Dr. Alonso was trying to solve. The prior art includes the following:

1. Prior patents that issued before September 22, 1994;
2. Prior publications having a publication date before September 22, 1994;
3. U.S. patents that have a filing date prior to September 22, 1994;
4. Anything in public use or on sale in the United States before September 22, 1994; and
5. Anything that was publicly known in the United States or described in a printed publication in the United States or a foreign country before the invention date.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.1 (2004).

**4.5.2 BAXTER'S CONTENTIONS (OBVIOUSNESS) (DISPUTED)**

The prior art that you have considered previously for anticipation purposes is also prior art for obviousness purposes. Additionally, the following references are also within the scope and content of the prior art and relevant to your determination of obviousness:

1. U.S. Patent No. 4,396,608 (Tenold) ("the Tenold reference");
2. Barandun, S. *et al.*, Intravenous Administration of Human  $\gamma$ -Globulin, *Vox Sang.* 7:157-174 (1962) ("the Barandun reference");
3. Wickerhauser, M. and Hao, Y., Large Scale Preparation of Macroglobulins, *Vox Sang.* 23:119-125 (1972) ("the Wickerhauser reference");
4. Louie, *et al.*, Inactivation of Hepatitis C Virus in Low pH Intravenous Immunoglobulin, *Biologicals* 22:13-19 (1994) ("the Louie reference").

Authority: 35 U.S.C. §§ 102, 103; Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8.1 (2004) (modified); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *SIBLA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356-57 (Fed. Cir. 2000); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716-17 (Fed. Cir. 1991); *Stratoflex, Inc. v. Aeroquip Corgi*, 713 F.2d 1530 (Fed. Cir. 1983); AIPLA's Model Patent Jury Instructions (2005).



**Talecris' Objection to Baxter's Proposed Instruction 4.5.2:**

Talecris objects to this instruction in its entirety and requests that it not be given to the jury. It is inappropriate for the Court to instruct the jury on any contentions of parties - the jury is to be instructed on the law to apply to the facts. Such an instruction takes the fact finding function away from the jury and there is also a significant risk of the jury thinking that the Court somehow endorses or is advocating for Baxter's positions.

**4.5.3 DIFFERENCES OVER THE PRIOR ART (STIPULATED)**

You must next consider the differences, if any, between the prior art and the claimed invention. Although it is proper for you to consider differences between the claimed invention and the prior art, you should not focus only on the differences, because the test is whether the claimed invention as a whole would have been obvious over all of the prior art. Each claim must be considered in its entirety.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.2 (2004).

#### **4.5.4 LEVEL OF ORDINARY SKILL (DISPUTED)**

##### **Baxter's Proposed Instruction 4.5.4:**

You must determine the level of ordinary skill in the art to which the claimed invention pertains. You must determine this level of skill as of September 22, 1995. Factors to be considered in determining the level of ordinary skill in the pertinent art include the educational level of the inventor, the types of problems encountered in the art, the prior art patents and publications, the activities of others and prior art solutions to the problems encountered by the inventor, the sophistication of the technology, and the education of others working in the field. A person of ordinary skill in the art is a person of ordinary creativity, not an automaton.

Talecris contends that a person of ordinary skill in the art is one or more scientists, each with an earned doctoral degree and several years of postdoctoral experience in the fields of antibody biochemistry, protein purification or process manufacturing, and/or clinical treatment of humans using IGIV.

Baxter contends that a person of ordinary skill in the art is a process chemist, biochemist, or immunologist (or the equivalent) with either: (1) a Bachelor's or Master's degree in chemistry, biology, biochemistry, immunology, or related field, and several years of experience in one or more of the following: (a) the purification of blood proteins, including fractionation; (b) virus removal or inactivation techniques, including solvent/detergent treatment and low pH incubation; and (c) the complement system and/or ACA, including how to measure and lower ACA; or (2) the equivalent of (1). This level of ordinary skill could be met either by an individual or by a group of people who satisfy the above criteria.

Based on the factors listed and the evidence presented, you must determine the level of ordinary skill in the art. You must apply the same standard when reaching your determinations as to whether the asserted claims of the '191 patent are invalid for obviousness as you apply in your infringement determinations.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8.3 (2004) (modified); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*41 (April 30, 2007); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006); *Orthopedic Equipment Co. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983); AIPLA's Model Patent Jury Instructions (2005).

**Talecris' Objection to Baxter's Proposed Instruction 4.5.4:**

Talecris objects to this instruction in its entirety. Talecris' proposed instruction accurately states the law, and further, it is inappropriate for the Court to instruct the jury on any contentions of parties - the jury is to be instructed on the law to apply to the facts. Baxter's proposed instruction does not accurately reflect the holding of the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007).

**Talecris' Proposed Instruction 4.5.4:**

Next, you are to determine the level of ordinary skill in the art to which the claimed invention pertains at the time the claimed invention was made. Factors to be considered in determining the level of ordinary skill in the pertinent art include: the education level of the inventor; the types of problems encountered in the art; the prior art patents and publications; the activities of others and prior art solutions to the problems encountered by the inventor; the sophistication of the technology, and the education of others working in the field.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.3 (2004).

**Baxter's Objection to Talecris' Proposed Instruction 4.5.4:**

Baxter objects to Talecris' proposed instruction as misleading and incomplete in view of recent developments in the law. *See* Baxter's Objections to Talecris' Proposed Final Jury Instruction No. 4.5. The Supreme Court expressly stated that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *See KSR International Co. v. Teleflex Inc.*, No 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*41 (April 30, 2007). The Supreme Court held that the Federal Circuit's "teaching, suggestion, or motivation" test for combining prior art references is too narrowly applied if the ordinary creativity of a person of skill in the art is disregarded. *Id.* Talecris' refusal to include language to this effect could mislead the jury into applying the test too narrowly, to Baxter's prejudice, in violation of Federal Rule of Evidence 403.

#### **4.5.5 OBJECTIVE CRITERIA CONCERNING OBVIOUSNESS (STIPULATED)**

In making your decision as to obviousness or non-obviousness of the claimed invention, you must consider the following objective evidence which may tend to show non-obviousness of the asserted claims:

1. Commercial success or lack of commercial success of products covered by the '191 patent;
2. A long-felt and unsolved need in the art which was satisfied by the invention of the '191 patent;
3. The failure of others to solve the problem addressed by the invention;
4. Copying of the invention by others in the field;
5. Unexpected results achieved by the invention;
6. Praise of the invention by Baxter or others in the field;
7. Expressions of disbelief or skepticism by those skilled in the art upon learning of the invention; and
8. Whether the inventor proceeded in a direction contrary to the accepted wisdom of those skilled in the art.

However, there must be a connection between the evidence showing any of these factors and claims 1 and 7 of the '191 patent if this evidence is to be given any weight or significance when arriving at your conclusion on the obviousness issue. For example, if commercial success is due to advertising, promotion, market position, salesmanship or the like, or is due to qualities or features of the product other than those claimed in the '191 patent, then any commercial success may have no relation to the issue of obviousness.



Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.6 (2004).

#### **4.5.6 MOTIVATION TO COMBINE (DISPUTED)**

##### **Baxter's Proposed Instruction 4.5.6:**

References may be combined to show obviousness if there is some motivation or suggestion to combine the references and if the combination would be reasonably likely to achieve the goal of the invention.

A suggestion or motivation to combine prior art references may be express or implied. For example, a suggestion or motivation to combine or modify the teachings of prior art references may be derived from the prior art references themselves, from the knowledge a person of ordinary skill in the art, or from the nature of the problem to be solved. Any need or problem known in the field of endeavor at the time of invention and addressed by the patent may also provide a reason for combining the elements in the manner claimed.

Alternatively, a combination of references can be suggested or motivated by reasons other than those contemplated by the inventor and still render an asserted claim obvious. Familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. To determine whether there was an apparent reason to combine known elements in the prior art in the fashion claimed by the patent at issue you may consider the interrelated teachings of multiple patents, the effects of demands known to the community or present in the marketplace and the background knowledge possessed by a person of ordinary skill in the art.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8.4, 4.8.5 (2004) (modified); *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*12, \*36, 39-41 and 43 (April 30, 2007); *Pfizer, Inc. v. Apotex, Inc.*, 82 U.S.P.Q.2d 1321, 1331, 1333 (Fed. Cir. 2007); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164 (Fed. Cir. 2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289-95 (Fed. Cir. 2006); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349 (Fed. Cir. 2000); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983); *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992); *Para-Ordnance Mfg., Inc. v. SGS Importers Int'l, Inc.*, 73 F.3d 1085 (Fed. Cir. 1999); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1369 (Fed. Cir. 2006); *In re Carlson*, 983 F.2d 1032, 1038 (Fed. Cir. 1992); *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986).

**Talecris' Objection to Baxter's Proposed Instruction 4.5.6:**

Talecris objects to Baxter's proposed instruction as argumentative, misleading, and biased, to Talecris' prejudice. Baxter's proposed instruction does not accurately reflect the holding of the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007).

**Talecris' Proposed Instruction 4.5.6:**

Once the prior art is assembled and considered, you should determine whether the prior art, considered as a whole, suggests the claimed invention. Prior art references may be combined to show obviousness if there is some motivation or suggestion to combine the references and if the combination would be reasonably likely to achieve the goal of the invention. Both the suggestion or motivation to combine and the expectation of success must be found in the prior art and for the same purpose.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.4 (2004)(modified); *Leapfrog Enters. v. Fisher-Price, Inc.*, 03-927-GMS (D. Del. March 30, 2006); *Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 98-80-SLR (D. Del. March 29, 2007); *Forest Labs. Inc. v. Ivax Pharms. Inc.*, 03-891-JJF (D. Del. July 13, 2006); *Boston Sci. Scimed, Inc. v. Cordis Corp.*, 03-283-SLR (D. Del. June 16, 2006).

**Baxter's Objection to Talecris' Proposed Instruction 4.5.6:**

Baxter objects to Talecris' proposed instruction as misleading and incomplete in view of recent developments in the law. *See* Baxter's Objections to Talecris' Proposed Final Jury Instruction No. 4.5. These recent cases (in particular, *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745 (April 30, 2007)) contain teachings critical to proper determination of the presence of a motivation to combine and omission of these teachings could bias the jury in favor of a finding of nonobviousness, to Baxter's prejudice in violation of Federal Rule of Evidence 403.

Baxter further objects that Talecris' proposed instruction contradicts the current state of the law. Talecris' proposed instruction incorrectly states that the suggestion or motivation to combine must be found in the prior art and for the same purpose. Talecris has cited no legal authority for its modifications and, indeed, Talecris' proposed instruction is contrary to the law. Federal Circuit law makes abundantly clear that motivation to combine need not be for the same purpose. *National Steel Car v. Canadian Pac. Railway*, 357 F.3d 1319, 1339 (Fed. Cir. 2004); *Pfaff v. Wells*, 124 F.3d 1429, 1439 (Fed. Cir. 1997). Talecris' proposed language further fails to inform the jury that the motivation to combine references can be express or implied. *See, e.g., Alza Corp. v. Mylan Labs, Inc.*, 464 F.3d 1286, 1289-95 (Fed. Cir. 2006); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004).

Baxter further objects that Talecris' proposed instruction fails to inform the jury that the motivation to combine may come from the knowledge of one of ordinary skill in the art or from the nature of the problem to be solved. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*,

464 F.3d 1356, 1369 (Fed. Cir. 2006); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 1289-90 (Fed. Cir. 2004).

#### **4.5.7 OBVIOUSNESS - HINDSIGHT (STIPULATED)**

A person of ordinary skill in the art is presumed to have knowledge of the relevant prior art at the time of the patentee's invention. If you find the available prior art shows each of the elements of the asserted claims, you must determine whether it would have been obvious to a person of ordinary skill in the art to combine or coordinate these elements in the same manner as the asserted claims.

You must resist the temptation to rely on hindsight while undertaking this evaluation. It is improper to use the '191 patent as a roadmap through the prior art references, combining the right references in the right way so as to achieve the result of the asserted claims. Rather, you must cast your mind back to the time of the invention and consider only the thinking of one of ordinary skill in the art, guided only by the prior art and what was known in the field.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.5 (2004) (modified).



#### **4.5.8 OBVIOUS TO TRY (DISPUTED)**

##### **Baxter's Proposed Instruction 4.5.8:**

The evidence might indicate to you that what the inventors did was obvious to try. If so, this does not indicate the '191 patent is invalid for obviousness. "Obvious to try" is not the standard, rather it is whether the invention as a whole would have been obvious to a person of ordinary skill in the inventor's field at the time he made his invention.

However, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options. If this leads to success, it is likely the product not of innovation but of ordinary skill and common sense. In this instance, the fact that a combination was "obvious to try" may demonstrate obviousness.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 4.8.7 (2004) (modified); *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*41-42 (April 30, 2007).

**Talecris' Objection to Baxter's Proposed Instruction 4.5.8:**

Baxter's proposed instruction is misleading and inaccurate. It elevates *dicta* from *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007) into binding statements of law and purports to apply the same as universal principles, applicable to all types of inventions, prior art, and technological context. *KSR* has little application to this case.

**Talecris' Proposed Instruction 4.5.8:**

The evidence might indicate to you that what the inventor did was obvious to try. If so, this does not indicate the '191 patent is invalid for obviousness. "Obvious to try" is not the standard; rather, it is whether the invention as a whole would have been obvious to those of ordinary skill in the pertinent art at the time he or she made the invention.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 4.8.7 (2004).

**Baxter's Objection to Talecris' Proposed Instruction 4.5.8:**

Baxter objects to Talecris' proposed instruction as misleading and incomplete in view of recent developments in the law. *See* Baxter's Objections to Talecris' Proposed Final Jury Instruction No. 4.5. The Supreme Court has ruled that constricted analysis under the "obvious to try" rule may improperly deny recourse to common sense and the ordinary creativity of a person of skill in the art, particularly in situations where there is a need to solve a problem and a finite number of identified, predictable solutions. *See KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), 550 U.S. \_\_\_\_ (2007), 2007 U.S. LEXIS 4745, at \*41 (April 30, 2007). Talecris' proposed instruction is wholly one-sided and could bias the jury against a finding of obviousness. Talecris' refusal to include balanced language in this instruction could mislead the jury into applying this instruction too narrowly, in violation of Federal Rule of Evidence 403.

#### **4.5.9 INDEPENDENT INVENTION BY OTHERS (BAXTER'S PROPOSED INSTRUCTION)**

In reaching your determination on the issue of obviousness, you should consider whether the subject matter of the '191 patent was also invented independently by other persons, either before the inventor of the '191 patent or at about the same time. Just as the failure of others to make the invention can be evidence of non-obviousness, independent making of the invention by a person other than the inventor prior to or about the same time can be evidence that the invention would have been obvious.

The simultaneous or near simultaneous invention by two or more people working independently may or may not be an indication of obviousness when considered in light of all the circumstances.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 3.3 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006), (modified); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1379 (Fed. Cir. 2000); *In re Farrenkopf*, 713 F.2d 714 (Fed. Cir. 1983); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983); ABA's Section of Patent, Trademark and Copyright Law (1987); AIPLA's Model Patent Jury Instructions (2005).

**Talecris' Objection to Baxter's Proposed Instruction 4.5.9**

Talecris objects to Baxter's proposed instruction in its entirety because "independent invention by others" has never been asserted by Baxter and the instruction is thus irrelevant. The instruction is highly likely to cause confusion because there is no evidence in the record regarding independent invention by others. This proposed instruction is therefore highly prejudicial to Talecris, and Talecris requests that it not be given.

#### **4.5.10 BAXTER'S CONTENTIONS (BAXTER'S PROPOSED INSTRUCTION)**

Baxter contends that each asserted claim of the '191 patent is obvious in view of the prior art.

Baxter contends that Claims 1 is obvious in view of at least:

1. The Tsay reference in combination with the Ng reference;
2. The Gehringer reference in combination with the Louie reference and/or the Ng reference;
3. The Ng reference in combination with the Wickerhauser reference and/or the Tsay reference;
4. The Prince reference in combination with the Tsay reference and/or the Tenold reference;
5. The Piet reference in combination with the Tsay reference, the Wickerhauser reference and/or the Louie reference;
6. The Eriksson reference in combination with the Tsay reference, the Ng reference and/or the Barandun reference;
7. The Biesert/Octagam EU/Octagam Israeli reference in combination with the Barandun reference, the Louie reference, the Tenold reference and/or the Hämäläinen reference;
8. The Venoglobulin/Yang/Uemura reference in combination with the Barandun reference; and/or
9. The Hämäläinen reference in combination with the Louie reference and/or the Tenold reference.

Baxter also contends that Claim 7 is obvious in view of at least:

1. The Tsay reference in combination with the Ng reference, the Louie reference, the Hämäläinen reference and/or the Barandun reference;
2. The Gehringer reference in combination with the Ng reference, the Louie reference and/or the Barandun reference;
3. The Ng reference in combination with the Louie reference and/or the Barandun reference;
4. The Prince reference in combination with the Louie reference and/or the Barandun reference;
5. The Piet reference in combination with the Louie reference and/or the Barandun reference;
6. The Eriksson reference in combination with the Louie reference and/or the Barandun reference;
7. The Biesert/Octagam EU/Octagam Israeli reference in combination with the Louie reference and/or the Barandun reference; and/or
8. The Venoglobulin/Yang/Uemura reference in combination with the Louie reference and/or the Barandun reference.



**Talecris' Objection to Baxter's Proposed Instruction 4.5.10:**

Talecris objects to this instruction in its entirety and requests that it not be given to the jury. It is inappropriate for the Court to instruct the jury on any contentions of parties - the jury is to be instructed on the law to apply to the facts. Such an instruction takes the fact finding function away from the jury and there is also a significant risk of the jury thinking that the Court somehow endorses or is advocating for Baxter's positions.

In addition, Talecris further objects to this instruction as it contains irrelevant information that is likely to confuse a jury.

## 5 UNENFORCEABILITY

### 5.1 INEQUITABLE CONDUCT (DISPUTED)

Every applicant for a patent has a duty of candor, good faith, **[and honesty]**<sup>11</sup> in its dealings with the Patent Office and the examiner handling the application. This duty of candor is important because the examiner has only limited information available to determine the state of the art. The time available to the examiner is also limited. Therefore, to prevent an applicant from obtaining a patent he does not deserve, the Patent Office requires full disclosure to the Patent Office of all information which is material to examination of the application. **[An applicant is chargeable with the knowledge and actions of his representatives.]**<sup>12</sup>

This means that the applicant and his attorneys must not intentionally withhold or misrepresent material information concerning the claimed invention. Each individual with such a duty must disclose all material information known to that individual. **[If information presents a close question as to materiality, the information should be disclosed to the**

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<sup>11</sup>Talecris objects to Baxter's proposed language as a misleading statement of the law. Baxter adds the term "honesty", when 37 C.F.R § 1.56(a) simply states that the "individual . . . has a duty of candor and good faith." While honesty may be implicit in candor and good faith, it is not a term used in 37 C.F.R § 1.56(a), and the addition of this word is unnecessary and confusing, to Talecris' prejudice.

<sup>12</sup>Talecris objects to Baxter's proposed language as an inaccurate statement of the law, biased in favor of Baxter, and therefore highly prejudicial to Talecris. Inequitable conduct is a fact specific inquiry, and therefore, Baxter should not be permitted to pick and choose language from inequitable conduct decisions that dealt with a particular set of facts that are not presently before this Court in order to mold the law to fit its case. To do so, would be to Talecris' prejudice. Therefore, Talecris proposes that the Court strike Baxter's proposed language from these instructions so that remaining language will be identical to the 1993 model instructions.

examiner, allowing him the opportunity to agree or disagree with the inventor's position.]<sup>13</sup> A breach of this duty is called inequitable conduct and renders the '191 patent unenforceable as a whole.

To prove inequitable conduct, Baxter must show by clear and convincing evidence that the Dr. Alonso or his attorney, Mr. Giblin, with intent to mislead or deceive, withheld or misrepresented information that was material to the examiner's evaluation of the patent application.

Baxter's Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.1 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006), (modified); *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 2007 U.S. App. LEXIS 11606 at \*73 (Fed. Cir. May 18, 2007); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1375-76, 1380, 1386 (Fed. Cir. 2001); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001); *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elec. Co., Ltd.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997); *Molins, PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 n.6 (Fed. Cir. 1995).

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<sup>13</sup>Talecris objects to Baxter's proposed language as misleading and prejudicial. A breach of the duty of candor and good faith concerns the withholding or misrepresentation of *material* information, not *questionable* information. The jury must ultimately determine whether withheld or misrepresented information concerning the claimed invention is material, not questionable. Therefore, Baxter's proposed language is prejudicial to Talecris.

Moreover, Baxter's proposed language deviates from the 1993 model instructions on inequitable conduct. Inequitable conduct is a fact specific inquiry, and therefore, Baxter should not be permitted to pick and choose language from inequitable conduct decisions that dealt with a particular set of facts that are not presently before this Court in order to mold the law to fit its case. To do so, would be to Talecris' prejudice. Therefore, Talecris proposes that the Court strike Baxter's proposed language from these instructions so that remaining language will be identical to the 1993 model instructions.

## 5.2 MATERIALITY (DISPUTED)

In evaluating an allegation that the applicant was guilty of inequitable conduct before the Patent Office, you must first determine whether there was any withholding or misrepresentation of information at all and, if so, whether the information withheld or misrepresented was indeed material. Information is not material if it is cumulative or adds little information to what the examiner already knew. In order for the information withheld or misrepresented to be material, there must be a substantial likelihood that a reasonable examiner would have considered it important in deciding whether to issue the '191 patent. **[Withheld information need not conclusively decide the issue of patentability to be material. Information is material if it refutes or is inconsistent with the information provided or arguments made by the applicant to persuade the examiner that the application was entitled to patent protection.]**

**Material information is not limited to prior art. It includes any information the examiner would consider important in evaluating the patentability of the claimed invention. If a reference presents a close question as to materiality, the reference should be disclosed to the examiner to allow him the opportunity to agree or disagree with the inventor's position. An applicant's knowledge that information was material may be established where the inventor submits that same information to the FDA but not to the PTO. Where an applicant knows of art or information, he cannot intentionally avoid learning of its materiality.]**<sup>14</sup>

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<sup>14</sup>Talecris objects to Baxter's proposed language as inaccurate, prejudicial, and biased in favor of Baxter. A breach of the duty of candor and good faith concerns the withholding or misrepresentation of *material* information, not questionable information. The jury must ultimately determine whether allegedly withheld or misrepresented information concerning

If you determine that there was a withholding or misrepresentation of information and that the information was material, then you must consider the element of intent. If, on the other hand, you find that Baxter has failed to prove by clear and convincing evidence that Dr. Alonso or Mr. Giblin withheld or misrepresented any material information, then you must find that there was no inequitable conduct.

**[Baxter contends that Dr. Alonso withheld information relating to two of his experiments from the Patent Office during prosecution, even as he knew them to be material to patentability:**

- 1. an experiment relating to solvent/detergent treatment at a pH level of 5.8 conducted on or before August 11, 1995, and submitted to the FDA as part of its PLA submissions for its Gamimune® N solvent/detergent treated product;**
- 2. an experiment relating to solvent/detergent treatment employing Tween 80 as a detergent, conducted on or before January 1993.**

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**the claimed invention is material.**

**Baxter's proposed language stating "An applicant's knowledge that information was material may be established where the inventor submits that same information to the FDA but not to the PTO" is contrary to applicable law. *See Pfizer Inc. v. Ranbaxy Labs Ltd.*, 405 F. Supp. 2d 495, 523 (D. Del. 2005). "A determination of materiality before the PTO is not governed by that which is required for submission to the FDA." Therefore, Baxter's instruction is wholly inappropriate and should be stricken.**

**Moreover, Baxter's proposed language deviates from the 1993 model instructions on inequitable conduct. Inequitable conduct is a fact specific inquiry, and therefore, Baxter should not be permitted to pick and choose language from inequitable conduct decisions that dealt with a particular set of facts that are not presently before this Court in order to mold the law to fit its case. To do so, would be to Talecris' prejudice. Therefore, Talecris proposes that the Court strike Baxter's proposed language from these instructions so that remaining language will be identical to the 1993 model instructions.**

Baxter contends that Dr. Alonso also withheld information relating to Gamimune® N, an immunoglobulin product which provided the starting point for Dr. Alonso's development of his solvent/detergent treatment process.

Baxter further contends that Mr. Giblin withheld the '771 patent, for which he was also the patent attorney, from the examiner during the prosecution of the '191 patent.

Baxter further contends that Mr. Giblin, Dr. Alonso, or both of them withheld the Ng reference from the examiner during prosecution of the '191 patent. Dr. Alonso knew of Ng's work, and Mr. Giblin previously was a patent attorney for patents listing Ng as an inventor.]<sup>15</sup>

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<sup>15</sup>Talecris objects to Baxter's proposed language as highly prejudicial. It is inappropriate for the Court to instruct the jury on any contentions of the parties – the jury is to be instructed on the law to apply to the facts. Such an instruction takes the fact finding function away from the jury. Baxter's proposed language invites the jury to conclude that facts are not in dispute, while in fact they are in dispute. For instance, Baxter's proposed first sentence which includes the language "even as he knew them to be material to patentability" invites the jury to assume that fact is not in dispute. Such language is highly prejudicial to Talecris. There is also a significant risk of the jury thinking that the Court somehow endorses or is advocating for Baxter's position.

Furthermore, even if the Court permits Baxter to include its contentions within the jury instructions, which Talecris maintains is inappropriate, Baxter's recited inequitable conduct allegations contradict their June 8, 2007 letter to Talecris regarding which individuals were being accused of which alleged acts of inequitable conduct and their Response to Talecris' Interrogatory 22 wherein Baxter was asked to set forth in detail Baxter's inequitable conduct allegations. First, in its Interrogatory Response, Baxter did not recite any allegation relating to Dr. Alonso allegedly withholding information relating to Gamimune® N, and yet Baxter proposes that this allegation be read to the jury. Such an instruction would be wholly prejudicial to Talecris. Second, Baxter represented to Talecris in both a letter to Talecris and its response to Interrogatory 22 that only Mr. Giblin was being accused of allegedly withholding the Ng reference. Yet, in this proposed instruction, Baxter is now claiming that either Dr. Alonso, Mr. Giblin, or both withheld the Ng reference. Such an instruction is contrary to Baxter's representations to Talecris, and therefore is wholly prejudicial to Talecris, particularly since Talecris recently deposed Mr. Giblin on the basis of Baxter's letter and Interrogatory Response.

Baxter's Authority: 37 C.F.R. § 1.56 (2003); Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.2 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006), (modified); *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 2007 U.S. App. LEXIS 11606 at \*44-46 (Fed. Cir. May 18, 2007); *Pharmacia Corp. v. Par Pharm.*, 417 F.3d 1369-1373 (Fed. Cir. 2005); *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1354-55 (Fed. Cir. 2005); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1375-76, 1380, 1386 (Fed. Cir. 2001); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000); *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elec. Co., Ltd.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000); *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321 (Fed. Cir. 1998); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997).



### 5.3 INTENT (DISPUTED)

#### Baxter's Proposed Instruction 5.3:

Baxter must prove, by clear and convincing evidence, that Dr. Alonso or Mr. Giblin withheld or misrepresented material information with the intent to mislead or deceive the patent examiner. While intent to deceive cannot be inferred from negligence, oversight, carelessness, or erroneous judgment alone, related facts may nevertheless have bearing on the totality of the circumstances.

Intent need not be proved directly because there is no way of scrutinizing the operations of the human mind. Therefore, you may infer intent from conduct, meaning that you may conclude that an individual intends the foreseeable results of his actions. Any such inference depends upon the totality of the circumstances, including the facts and circumstances, the nature and level of culpability of the conduct, and the absence or presence of affirmative evidence of good faith. Contemporaneous evidence may be probative of good faith or of intent to deceive. Mere speculative testimony as to good faith is less credible. Intent may be inferred when the inventor or his attorneys make an argument for patentability that could not have been made alongside the omitted information, withholds information relating to issues repeatedly raised during examination, or selectively withholds information from the Patent Office while disclosing that same information to the FDA. Intent may also be inferred from attorneys' deviations from normal or standard practice during prosecution.

A pattern of material nondisclosures can also weigh in favor of a finding of inequitable conduct.



Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.3 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006), (modified); *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 2007 U.S. App. LEXIS 11606 at \*34, \*51-53, \*44-46, \*67, \*76 (Fed. Cir. May 18, 2007); *Cargill, Inc. v. Canbra Foods, Ltd.*, 2007 U.S. App. LEXIS 3222 (Fed. Cir. Feb. 14, 2007); *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 394 F.3d 1348, 1354-55 (Fed. Cir. 2005); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1375-76, 1386 (Fed. Cir. 2001); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274-75 (Fed. Cir. 2001); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000); *Elk Corp. of Dallas v. GAF Building Materials Corp.*, 168 F.3d 28 (Fed. Cir. 1999); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997); *Merck & Co. v. Danbury Pharmacal*, 873 F.2d 1418, 1422 (Fed. Cir. 1989).

**Talecris' Objection to Baxter's Proposed Instruction 5.3:**

Talecris objects to Baxter's proposed instruction as prejudicial and biased in favor of Baxter.

The examples listed where intent may be inferred are prejudicial. The jury is already instructed to consider the totality of the circumstances, the nature and level of culpability of the conduct, and the absence or presence of affirmative evidence of good faith. By listing all the situations where a jury may infer deceit, the instruction focuses on a list of grievances that encourages the jury to consider each and every one, including irrelevant situations. There are also several situations where the jury cannot infer intent. *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006)(citations omitted) ("Intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent."); *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 348 F.Supp.2d 713, n. 15 (N.D.W.Va. 2004) ("[T]he Court cannot infer intent from the mere failure to submit material to the PTO that was later submitted to the FDA, because there are different standards for disclosure."). An inclusion of every factual situation is biased in favor of Baxter and prejudicial to Talecris.

Baxter's instruction that "you may infer intent from conduct, meaning that you may conclude that an individual intends the foreseeable results of his actions" is misleading. While attempting to further define intent, Baxter suggests as an affirmative statement that the jury may infer intent. This is unnecessarily confusing because it leaves open the interpretation that the jury *must* infer intent from conduct, and never informs the jury that they are not *required* to do so. See *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1262-1263 (Fed. Cir. 2001). Such an instruction is prejudicial to Talecris. Talecris's

proposed instruction alleviates this prejudice as it follows the 1993 model jury instructions without any deviations.

Baxter's instruction that "[m]ere speculative testimony as to good faith is less credible" mischaracterizes the law. The instruction is prejudicial because it suggests that speculative testimony is less credible to prove good faith than other evidence. In *McKesson*, the Court held that it was proper for the lower court to infer intent because a hindsight explanation was not credible. See 2007 WL 1452731, at \*12 (citing *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 2006 WL 1652518, \*18 (E.D.Cal. June 13, 2006)). The court was merely performing its evidentiary function, and not suggesting that speculative testimony as to good faith is less credible than speculative testimony as to other evidence. Baxter's instruction suggests that the jury should weigh this evidence in its favor, and therefore, prejudices Talecris.

The last sentence of Paragraph two is prejudicial to Talecris. "Inequitable conduct requires an intent to act inequitably." *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435 (Fed. Cir. 1991) (citing *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed.Cir.1987)). Baxter's instruction affirmatively declares that the mere deviation from normal or standard practice may allow intent to be inferred. This is highly suggestive and biased in favor of Baxter.

The last paragraph confuses the law. A pattern of material disclosures deals with equitable balancing, not intent. *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, --- F.3d ---, 2007 WL 1452731, at \*12 (Fed. Cir. May 18, 2007) ("As a final step, the court engaged in equitable balancing and concluded that the 'pattern of material

nondisclosures ... weighs firmly in favor of unenforceability,' because 'the showings of materiality and intent are high' with respect to each identified nondisclosure."'). Therefore, a pattern of material disclosures should not be considered as part of intent.

**Talecris' Proposed Instruction 5.3:**

Baxter must prove, by clear and convincing evidence, that Dr. Alonso or Mr. Giblin withheld or misrepresented material information with the intent to mislead or deceive the patent examiner. If the withholding or misrepresentation occurred through negligence, oversight, carelessness, or an erroneous judgment, then there was no intent and no inequitable conduct.

Intent need not be proved directly because there is no way of scrutinizing the operations of the human mind. Therefore, you may infer intent from conduct, from acts substantially certain to accomplish a result, but you are not required to infer it. Any such inference depends upon the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.3 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006).

**Baxter's Objections to Talecris' Proposed Instruction No. 5.3**

Baxter objects to Talecris' proposed instruction as presenting the jury with an incorrect statement of the law. Intent to mislead or deceive is determined under the totality of the circumstances. The Federal Circuit has only stated that gross negligence covers too wide a range of culpable conduct to create such an inference in all cases. Rather, grossly negligent conduct may or may not compel an inference of an intent to mislead, depending on the totality of the circumstances. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 876 (Fed. Cir. 1988). By comparison, Talecris' instruction that "if the withholding or misrepresentation occurred through negligence, oversight, carelessness, or an erroneous judgment, then there was no intent" wrongly suggests to the jury that such lapses constitute absolute excuses for material nondisclosures regardless of the totality of the circumstances. Such an instruction is prejudicial to Baxter. *See* Fed. R. Evid. 403.

Further, Talecris' instruction omits any reference to established and recently reaffirmed precedent regarding the materiality of information sent to regulatory agencies, the FDA in particular. *McKesson Information Solutions, inc. v. Bridge Medical, Inc.*, 2007 U.S. App. LEXIS 11606 at \*44-46 (Fed. Cir. May 18, 2007); *Merck & Co. v. Danbury Pharmacal*, 873 F.2d 1418, 1422 (Fed. Cir. 1989). Furthermore, the Federal Circuit holds that intent may be inferred when the applicant makes arguments for patentability that could not have been made alongside the undisclosed information. *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, inc.*, 326 F.3d 1226 (Fed. Cir. 2003). Talecris' instruction also fails to instruct that the withholding of information relating to issues repeatedly raised during examination also supports an inference

of intent to deceive. *Cargill, Inc. v. Canbra Foods, Ltd.*, 2007 U.S. App. LEXIS 322 (Fed. Cir. Feb. 14, 2007).

#### **5.4 BALANCING (STIPULATED)**

You must determine whether the withheld information or misrepresentation satisfies a threshold level of materiality. You must also determine whether the conduct of Dr. Alonso or Mr. Giblin satisfies a threshold showing of intent to mislead. Assuming satisfaction of the thresholds, materiality and intent must be balanced.

The more material the withheld or misrepresented information is, the less stringent is the requirement to prove intent by clear and convincing evidence. In other words, withholding or misrepresentation of a highly material piece of information requires a lower level of proven intent, thereby allowing you to infer intent. You must be the judge of this balance.

If you find that Baxter has proved by clear and convincing evidence that there was a material withholding or a material misrepresentation of information and that Dr. Alonso or Mr. Giblin acted with intent to deceive the examiner, then you must balance these two factors to determine whether or not, in your view, there was inequitable conduct.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.4 (Mar. 1993), available at <http://www.ded.uscourts.gov/JuryMain.htm> (Rev. 3/24/2006), (modified).



## **6 DAMAGES**

### **6.1 GENERALLY (STIPULATED)**

If, after considering all of the evidence and the law as I have stated it, you have determined either that: (1) claim 7 is not infringed by Baxter; or (2) claim 7 is invalid or the '191 patent is unenforceable, then your verdict should be for Baxter and you need go no further in your deliberations. If you have found that claim 7 is infringed and valid and the '191 patent enforceable, you should then turn to the issue of damages.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 5.1 (2004).

**6.2 COMPENSATORY DAMAGES IN GENERAL (STIPULATED)**

The patent laws provide that in the case of infringement of a valid patent claim, the exclusive licensee shall be awarded damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer. Damages are compensation for all losses suffered as a result of the infringement.

There are two common but alternative methods for computing damages in a patent infringement case. One is called “lost profits” damages and the other is called “reasonable royalty” damages. In this case, Talecris is not seeking lost profits.

It is not relevant to the question of damages whether Baxter benefitted from, realized profits, or even lost money as a result of the acts of infringement. It is also not relevant if Baxter did not foresee that it would cause Talecris damage at the time that it infringed the asserted claims. Thus, the only issue is the amount proven to adequately compensate Talecris for Baxter’s infringement based on a reasonable royalty. Adequate compensation should return Plaintiff to the position it would have occupied had there been no infringement.

Authority: Draft Uniform Jury Instructions For Patent Cases in the United States District of Delaware at 5.1, 5.2, 5.5 (2004) (modified).

### 6.3 BURDEN OF PROOF (DISPUTED)

Talecris has the burden of proving damages by what is called a preponderance of the evidence and is entitled to all damages that can be proven with “reasonable certainty.” On the one hand, reasonable certainty does not require proof of damages with mathematical precision. Mere difficulty in ascertaining damages is not fatal to Talecris’ right to recover. On the other hand, Talecris is not entitled to speculative damages; that is, you should not award any amount of loss that, although possible, is wholly remote or the result of mere conjecture. You may base your evaluation of reasonable certainty on opinion evidence. **[Any doubts regarding the computation of the amount of damages should be resolved against Baxter and in favor of Talecris.]**<sup>16</sup>

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 5.3 (2004).

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<sup>16</sup>Baxter objects to this sentence as misleading, prejudicial, and biased in favor of the patentee in violation of Federal Rule of Evidence 403. This sentence at the end of this instruction could unfairly bias the jury towards finding damages should there be any doubt, to Baxter’s prejudice.

**6.4 DATE DAMAGES MAY BEGIN (STIPULATED)**

In this case, if you find claim 7 is valid and infringed, you should begin calculating damages as of September 26, 2005.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 5.4 (2004) (modified).

## 6.5 REASONABLE ROYALTY AS A MEASURE OF DAMAGES (DISPUTED)

In this case, Talecris is seeking damages in the amount of a reasonable royalty. A reasonable royalty is an amount of money that someone pays a patentee to be able to use the patented invention.

A reasonable royalty is the minimum permissible measure of damages set by the patent law and is not necessarily the actual measure of damages, but is merely the floor below which damages may not fall. **[Accordingly, you may find damages in excess of a reasonable royalty if you find that the facts so warrant, but you may not award less than a reasonable royalty.]<sup>17</sup>**

A reasonable royalty is the amount of money that would be agreed to in a hypothetical arm's-length negotiation between Talecris and Baxter, with both operating under the assumption that the negotiated patent is valid and would be infringed by the accused process and product. The reasonable royalty must be calculated as of the point in time just prior to when infringement would begin.

In the hypothetical arm's-length negotiation, you must assume that both parties are willing participants. You must assume that the person negotiating on behalf of Baxter was willing to take a license and would have known that the asserted claims were valid, enforceable, and infringed by Baxter. You must also assume that Talecris would have been willing to grant a license. **[Further, you must assume that the parties would have contemplated two situations: (1) Baxter was willing to take a license and stop using the**

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<sup>17</sup>**Baxter objects to this sentence as misleading, inaccurate and prejudicial because Plaintiffs are only asserting reasonable royalty so there is no measure by which the jury is allowed to increase damages above reasonable royalty.**

**‘191 patent as of the time of trial; or (2) Baxter was willing to take a license but would continue to use the ‘191 patent for the entire life of the patent.]<sup>18</sup>** Finally, you must assume that both Talecris and Baxter knew all pertinent information at the time of the hypothetical negotiation.

Having that in mind, you may consider events after the date the infringement began and any other relevant fact as a basis for determining the reasonable royalty for Baxter’s use of the patented invention, including the opinion testimony of experts.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware (2004) p.76 (modified); *Ebay Inc. v. Mercexchange, LLC*, 126 S.Ct. 1837 (2006); *Praxair, Inc. v. ATMI, Inc.*, 2007 U.S. Dist. LEXIS 21589 (D. Del. Mar. 27, 2007); *St. Clair Intellectual Property Consultants, Inc. v. Canon, Inc.*, 2004 U.S. Dist. 19475 (D. Del. Sep. 28, 2004).

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<sup>18</sup> **Baxter objects to the instruction on alternative royalty rates as contrary to reasonable royalty analysis under *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970) and for the reasons stated in Baxter’s Motion In Limine No. 5 (D.I. 251 and 354).**

**Talecris responds that Baxter’s objection is an impermissible attempt to reargue its Motion in Limine No. 5, which the Court denied, and its Motion for Reconsideration of the Court’s denial of its Motion in Limine No. 5, which the Court denied, and the Court’s July 3 Order, wherein the Court stated that if any party felt as though an evidentiary ruling needed to be revisited, the issue should be raised at trial. At this point, all of Baxter’s objections to the “alternative injunction” scenarios have been fully aired and rejected by the Court, and it is a flagrant abuse of the meet and confer process to reargue them herein, under the guise of objections to jury instructions.**

**6.6 HYPOTHETICAL NEGOTIATION - BAXTER STOPS USING THE '191 PATENT AS OF THE TIME OF TRIAL (DISPUTED)**

**Talecris' Proposed Instruction:**<sup>19</sup>

Assuming during the hypothetical negotiation that the parties would have contemplated that Baxter would be willing to take a license from the time of the hypothetical negotiation until the time of trial, you may consider evidence on any of the following factors in determining the amount of a reasonable royalty:

**Baxter's Proposed Instruction:**<sup>20</sup>

In determining reasonable royalty, you can consider the following factors, which the attorneys and experts may refer to as the "*Georgia-Pacific* factors":

**Stipulated:**

1. The royalties received by Talecris and Bayer for licensing others under the '191 patent or other patents comparable to the '191 patent;
2. The rates paid by Talecris, Baxter, or others for the use of other patents comparable to the '191 patent;
3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of territory, or with respect to whom the manufactured product may be sold;

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<sup>19</sup> Baxter objects to the introduction of this instruction as misleading, inaccurate and prejudicial. *Georgia-Pacific* factors are relevant for all reasonable royalty analysis and not just when a defendant takes a license that requests stop using the accused process.

<sup>20</sup> Talecris objects to Baxter's proposed language because it purposefully ignores the Court's ruling on Talecris' Motion *in Limine* No. 5 (D.I. 251) and the Court's denial of reconsideration (D.I. 363). Talecris' proposed language both accurately reflects the current state of the law and comports with the Court's rulings.

4. Whether Talecris and Bayer have or had an established policy and marketing program to maintain their patent exclusivity by not licensing to others to use the invention or by granting licenses under special conditions designed to preserve that exclusivity;
5. The commercial relationship between Talecris and Baxter, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventors or promoters;
6. The duration of the patent and the length of the licenses;
7. The established profitability of the product made under the patent, its commercial success, and its current popularity;
8. The utility and advantages of Talecris' patented invention over the old modes or devices, if any, that had been used for working out similar results;
9. The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by Talecris, and the benefits to those who have used the invention;
10. The extent to which Baxter has made use of the invention, and any evidence that shows the value of that use;
11. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions;
12. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process,



business risks, or significant features or improvements added by Baxter;

13. The opinion testimony of qualified experts; and
14. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware 5.14.1 (2004) (modified).

**6.7 HYPOTHETICAL NEGOTIATION - BAXTER CONTINUES USING THE  
'191 PATENT FOR THE DURATION OF THE LIFE OF THE PATENT  
(TALECRIS' PROPOSED INSTRUCTION)**

Assuming during the hypothetical negotiation that the parties would have contemplated that Baxter would be willing to take a license but would continue to use the '191 patent for the duration of the life of the patent, the reasonable royalty rate must account for Baxter's continued presence in the marketplace with the accused product under compulsory license from Talecris. In such a situation, the parties would have considered the anticipated lost profits that Talecris would expect to realize in the future due to the presence of Baxter's GAMMAGARD® Liquid in the market and its resulting impact on a reasonable royalty.

In order to analyze the value of such future lost profits, Talecris must show:

1. There is a demand for the patented product;
2. Talecris has the ability to meet the market demand;
3. No acceptable non-infringing substitutes are or will become available; and
4. The amount of profit Talecris would make.

Talecris need not negate every possibility that purchasers of Baxter's products might buy another product or no product at all. The mere existence of a competing device does not make that product an acceptable substitute. To be an acceptable non-infringing substitute, a proposed competitive substitute must be both "available" and "acceptable." A non-infringing substitute is "available" if the infringer had all of the necessary equipment, know-how, and experience to use the alternative during the time of infringement as well as the economic

incentive to do so. To be “acceptable,” a non-infringing substitute must have had the advantages of the patented technology.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware (2004), p.70 (modified); *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341, 1346-49 (Fed. Cir. 1999); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1123 (Fed. Cir. 2003); *Standard Havens Prods. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991).

**Baxter's Objection to Talecris' Proposed Instruction 6.7:**

Baxter objects to the proposed instruction as an misleading, incomplete and inaccurate statement of the law:

(1) The title and instruction on alternative royalty rates is contrary to reasonable royalty analysis under *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970) and for the reasons stated in Baxter's Motion In Limine No. 5 (D.I. 251 and 354). None of Plaintiffs' authorities considered the *Panduit* factors to determine reasonable royalty. Without waiving any objections, Baxter proposes that the introduction be changed to: "Assuming during the hypothetical negotiation that the parties would have contemplated that Baxter would be willing to take a license but would continue to use the '191 patent for the duration of the life of the patent, you may consider in determining the reasonable royalty the anticipated lost profits that Talecris may expect to realize in the future for the continued use of the '191 patent."

(2) Reference to Baxter's GAMMAGARD Liquid product is misleading and inaccurate since Claim 7 is a method claim and not a product claim.

(3) The word "infringer" in the context of discussing Baxter is prejudicial in violation of Federal Rule of Evidence 403.

(4) The entire third paragraph discussing Talecris' burden of proof and non-infringing substitutes is an inaccurate statement of law. See *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1166 (Fed. Cir. 1991). Contrary to Talecris' proposed instruction, a non-infringing substitute is available if it is in the marketplace, irrespective of

whether the accused infringer possessed all of the necessary equipment, know-how, and experience. *See SmithKline*, 926 F.2d at 1166.

**6.8 INTEREST (STIPULATED)**

None of the parties' calculations include interest. Therefore, in arriving at your damage calculation, you should not consider interest in any way because it is the function of the Court to award interest.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 5.15 (2004).

**6.9 CLOSING STATEMENT - DAMAGES (STIPULATED)**

The fact that I have instructed you regarding damages should not be construed as suggesting which party is to prevail in this case. Instructions regarding damages are given for your guidance in the event that the evidence leads you to find in favor of Talecris. Finally, if you find Talecris is entitled to damages, you may not include or add to the award any sum for purposes of punishing Baxter or to set an example.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 5.16 (2004) (modified).

**7 DELIBERATIONS AND VERDICT**

**7.1 INTRODUCTION (STIPULATED)**

My instructions on the law are now finished. I will end by explaining how you will conduct your deliberation in the jury room and about your possible verdicts.

When you start deliberating, do not talk to the jury officer, to me, or to anyone but each other about the case. If you have any questions or messages, you must write them on a piece of paper, sign them, and give them to the jury officer. The officer will then give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror Number 1.

One more thing about messages. Never write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. Your votes should stay secret until you are finished.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 6.1 (2004).



## **7.2 UNANIMOUS VERDICT (STIPULATED)**

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after an impartial consideration of the evidence with your fellow jurors. Talk with each other, listen carefully and respectfully to everyone's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not surrender your honest convictions as to the weight or effect of evidence solely because of the opinion of your fellow jurors or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges - judges of the facts, and, in the end, your vote must be exactly that - your own vote. Your sole interest is to seek the truth from the evidence in this case.

A verdict form has been prepared for you. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in and date the form, and you will all sign the form. You will then return to the courtroom and your foreperson will give your verdict.

It is proper to add the caution that nothing said in these instructions and nothing in the verdict form is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is the sole and exclusive duty and responsibility of the jury.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware (2004) p.83 (modified).

**7.3 DUTY TO DELIBERATE (STIPULATED)**

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to consult with each other, talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 6.3 (2004) (modified).

**7.4 COURT HAS NO OPINION (STIPULATED)**

Let me finish by repeating something that I said to you earlier. Nothing that I have said or done during this trial, nothing about my instructions, and nothing about the form of the verdict was meant to convey what I think your verdict should be or to influence your decision in any way. You must decide the case yourselves based solely on the evidence presented.

Authority: Draft Uniform Jury Instructions for Patent Cases in the District of Delaware at 6.4 (2004).

**CERTIFICATE OF SERVICE**

I hereby certify on this 8th day of July, 2007 I electronically filed the foregoing PLAINTIFFS' BRIEF IN OPPOSITION TO BAXTER'S MOTION FOR RECONSIDERATION OF ORDER GRANTING MOTION FOR SUMMARY JUDGMENT THAT THE CLAIMS OF THE '191 PATENT ARE NOT INDEFINITE with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on July 8, 2007.

<b><u>Via Hand Delivery and E-Mail</u></b> Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	<b><u>Via Federal Express and E-Mail</u></b> Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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*Attorneys for Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC*

**CERTIFICATE OF SERVICE**

I hereby certify on this 9th day of July, 2007 I electronically filed the foregoing JOINT PROPOSED FINAL JURY INSTRUCTIONS with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on July 9, 2007.

<b><u>Via Hand Delivery and E-Mail</u></b> Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	<b><u>Via Federal Express and E-Mail</u></b> Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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